

9/463586

Docket No.: 515-4183

420 Rec'd PCT/PTO 25 JAN 2000

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of )  
Maurizio Valeri et al ) Group Art Unit:  
Serial No.: not known ) Examiner:  
Filed: not known )

For: PHARMACEUTICAL COMPOSITIONS CONTAINING VITAMIN D AND  
CALCIUM, THEIR PREPARATION AND THERAPEUTIC USE

New York, NY 10036  
January 25, 2000

Assistant Commissioner for Patents  
Washington, D.C. 20231

#5A  
AKD  
6-30-00

PRELIMINARY AMENDMENT

Sir:

This Amendment is being filed to reduce the filing fee of the above identified application. Kindly amend the subject application as follows:

IN THE CLAIMS

Kindly amend claims 3, 13 and 14 under the provisions of 37 CFR§1.121(a) by deleting the bracketed subject matter and inserting the underlined material;

*a<sup>1</sup>*  
3. (amended) Pharmaceutical composition according to Claim[s] 1 [and 2], in which the calcium salt is calcium phosphate.

*a<sup>2</sup> Sub B2*  
13. (amended) Process for the preparation of a pharmaceutical composition according to Claim[s] 1 [and 7], characterized by the following steps:

- a) In a granulator turning at high speed, distribut[e]ing the binding agent, consisting of propylene glycol or low molecular-weight polyethylene glycols over the calcium salt[.];
- b) Adding the colloidal silica, approximately 25% of the mannite, the citric acid, and the sodium saccharin, and mixing

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for the time required and at the appropriate speed[.];  
c) Adding the mixture, prepared separately, consisting of sucrose palmitate, a suspending agent, flavoring, colouring agent, the remaining part of the mannite and the Vitamin D<sub>3</sub>, and mixing together with the rest of the preparation[.]; and  
d) Distribut[e]ing the granulate thus obtained into bags.

14. (amended) Process for the preparation of a pharmaceutical composition according to Claim[s] 1 [and 8], characterized by the following steps:

a) In a granulator turning at high speed, [distribute] placing the binding agent, consisting of liquid parafin or silicon oil, over the calcium salt[.].  
b) Adding in order, to a mixture of colloidal silica, carboxymethyl cellulose and sodium saccharin previously sifted, the Vitamin D<sub>3</sub> and the sorbitol, mixing thoroughly every time before a new ingredient is added [.] , and [P]ouring the mixture into the rotating granulator and mixing for the required time and at the appropriate speed[.]; and  
c) Compressing the granulate to the required weight to obtain the desired tablets.

REMARKS

This Amendment is being filed to delete the multiple dependent claims and reduce the filing fee. It is requested that this Amendment be entered prior to calculating the filing fee.

Respectfully submitted,

  
James V. Costigan  
Registration No. 25,669

HEDMAN, GIBSON & COSTIGAN, P.C.  
1185 Avenue of the Americas  
New York, NY 10036  
(212) 302-8989